

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA ex rel.  
LAURIE SIMPSON,

Plaintiff,

vs.

BAYER CORPORATION, et al.,

Defendants.

Civil Action No.: 05-3895 (JMV)(MF)

**REPORT AND RECOMMENDATION OF  
THE SPECIAL MASTER**

The matter before the Special Master is a motion filed by Defendants, Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc. and Bayer Healthcare, LLC (collectively, “Bayer”).<sup>1</sup> The Defendant seeks to compel the U.S. Government (“Government”), a non-party, to “participate in discovery.” The Government opposes Defendant’s motion and has filed a cross-motion to quash subpoenas served by Defendant.

The undersigned has reviewed Bayer’s brief and exhibits in support of the motion, the Government’s brief and exhibits in opposition and in support of its cross-motion, and Bayer’s reply brief.

After considering submissions of the parties, based upon the following, it is the opinion of the Special Master that Defendant’s motion is granted in part and denied in part and the Government’s cross-motion is granted in part and denied in part.

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<sup>1</sup> For the purposes of this motion, the Bayer entities will be referred to in the singular, “Bayer” or “Defendant.”

## **I. DISCUSSION**

This is a *qui tam* action brought by Plaintiff-Realtor Laurie Simpson (“Realtor”) under the whistleblower provisions of the False Claims Act (“FCA”), 31 U.S.C. § 3729, et seq. on August 5, 2005. The Government has declined to intervene. Realtor alleges that Bayer caused the submission of false claims to Federal health programs related to a pharmaceutical, Trasylol, by marketing that medication for off-label uses that were not reasonable and necessary and by paying kickbacks to physicians and other healthcare professionals to induce increased use of that medication. Additional and more detailed allegations concerning this dispute have been set forth in a number of other documents including Opinions of the Court and Reports and Recommendations by the Special Master and will not be repeated here. However, the allegations previously summarized, as noted, form the basis of the lawsuit and the underpinnings for this motion and cross-motion.

This dispute arises out of Defendant’s service of subpoenas on five Government agencies – (1) the Centers for Medicare and Medicaid Services (CMS); (2) the Food and Drug Administration (FDA); (3) the Department of Justice (DOJ); (4) the Department of Defense (DOD); and (5) the Department of Veterans Affairs (VA). The subpoenas were served at different times but date back at least two years starting with a subpoena served on CMS on August 17, 2018. Defendant contends that the agencies’ responses are either inadequate or wholly lacking despite the fact that its attorneys have generated efforts to narrow the scope of the subpoenas to minimize the burden on the Government. The Government, on the other hand, maintains that its agencies have adequately responded to the subpoenas, that Defendant’s

attempts to “narrow” the demands are empty, that the subpoenas generally seek information which has no bearing on the issues of this lawsuit and that the response is unduly burdensome.

## **II. DEFENDANT’S ARGUMENT**

In support of its position, Bayer asserts that throughout approximately 25 years of litigation, the Government has been actively involved in this *qui tam* lawsuit involving violations of the FCA filed by Realtor, a former Bayer employee. Although the Government has declined to intervene, Bayer insists that it remains the real party in interest and any recovery flows in its direction. Instead of taking a back seat, says Bayer, the Government has been actively involved by filing statements and briefs, participating in oral argument and demanding documents from Defendant during informal discovery.

Defendant also relies upon the opinion of Judge Linares entered on April 23, 2019, which denied motions for partial summary judgment by Defendant and by Realtor. Bayer states that the Court agreed with the position taken by the Government in its filings that materiality is a fact based inquiry and that “Realtor must provide ‘evidence that [Bayer] knows the Government consistently refuses to pay claims in the mine run of cases based upon non-compliance with’ the AKS (Anti-Kickback Statute) or the reasonable and necessary requirement as it relates to off-label drug uses.” Again, citing the decision, Bayer insists that the focus is on the Government’s actual or likely conduct in terms of paying claims that are non-compliant.

Bayer maintains that the material it seeks is relevant to the three remaining claims here: (1) that Bayer caused the submission of false claims by marketing Trasylol for improper off-label uses; (2) that Bayer paid kickbacks to promote its use of Trasylol and another medication, Avelox, violating the AKS; and (3) that Bayer retaliated against Realtor by terminating her.

According to Defendant, its subpoenas while containing some distinctions in the requests, fundamentally ask for the following materials:

- Materials demonstrating whether the Government ever denied payment based upon violation of the AKS or off-label rules.
- Materials demonstrating whether the Government had actual knowledge that certain requirements were violated but still paid claims.
- Materials as to the Government's own off-label use of Trasylol and policies regarding such use.
- Materials demonstrating whether Government employees were permitted to attend conferences hosted by pharmaceutical companies, including any policies relating to such attendance.

Citing *Federal Rule of Civil Procedure* 45(d)(2)(B)(i)<sup>2</sup>, Bayer argues that a party may move for an order compelling production when a subpoenaed party fails to respond and that the scope of discovery is the same as under *Rule* 26, i.e., the party must produce “non-privileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case.” Furthermore, under *Rule* 45, in assessing the burden of a subpoena, the courts need to consider the interest of the non-moving party in the outcome of the case. As noted, Bayer insists that the Government is the real party in interest here and would receive the majority of any recovery.

Defendant maintains that the five subpoenaed agencies have made only limited productions or none and have refused to correct gaps in production. As to each subpoena, Defendant argues as follows.

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<sup>2</sup> All subsequent references to a Rule are references to a Federal Rule of Civil Procedure.

As to CMS, which has produced 250 documents<sup>3</sup>, Bayer insists that most documents were outside the relevant time frame and not actually responsive. It has requested documents showing the denial of any claims related to Trasylol or Avelox due to kickback or off-label violation. Additionally, Defendant asked CMS to produce policies as to how the agency would learn of an improper use and factors leading to a denial for which, Bayer says, a single document has been provided. Defendant also sought information as to how CMS investigates violations before paying a claim.

Defendant maintains that CMS has no proportionality defense since the Government would receive the majority of any recovery and the burden pales compared to the alleged damages. Further, “Bayer has repeatedly proposed that CMS simply stipulate that it has never denied payment for a drug based upon allegations of AKS violations or off-label use and that it has no policies or procedures to do so.” To this inquiry, there has been no response.

As to the DOJ (no documents), Bayer seeks materials showing whether that agency has had any involvement in a decision to pay or deny a claim, in particular documents between the DOJ and CMS. Defendant further requested materials relating to the Government’s “actual knowledge” of the allegations and documents relevant to whether “Bayer’s conferences were proper or could be considered unlawful kickbacks.” Again, Bayer argues that this agency has no defense based upon burdensomeness and further that Bayer produced a draft stipulation agreeing to withdraw its subpoena if the DOJ conceded that it knew of the FCA violations by August 5, 2005 [filing of suit] and it did not participate in any decision on claims submitted to Medicare or Medicaid. In response, the DOJ stated it was prepared “to seek approval to represent” that there

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<sup>3</sup> The parties have provided different figures as to the numbers or pages of documents produced. This is something which the Special Master cannot resolve here.

was no evidence that it was involved in payment decisions as to Trasylol and Avelox and that it is “not normally involved” in CMS’s payment decisions. Bayer maintains that the DOJ “should be ordered to confirm these simple facts or to produce documents responsive to Bayer’s requests.”

As to the FDA (302 documents), many are said to be irrelevant or dated outside the stipulated time and consequently, Bayer posed follow up questions to confirm that this agency had no documents showing it had participated in CMS’s approval or denial of claims. Bayer maintains that these inquiries are relevant as to whether the FDA had any involvement in the decision making process, i.e., whether it instructed CMS to deny claims due to improper use or a kickback.

Finally, as to the DOD and VA (no documents), Bayer seeks to know whether and how hospitals run by these agencies used Trasylol for off-label procedures. To wit, “[i]f physicians at Government-run hospitals were using Trasylol for off-label uses, that would tend to show that such uses were not unreasonable and unnecessary.” Bayer sought information as to the agencies’ policies regarding employees’ attendance at conferences run by third parties which would impact the claim that attendance was a form of a disguised kickback. Hence, “DOD and VA should be compelled to produce relevant documents, confirm that they have none, or – at a minimum – meet and confer with Bayer to discuss its document requests[.]”

### **III. THE GOVERNMENT’S ARGUMENT**

As noted, the Government opposes Bayer’s motion and cross-moves to quash the subpoenas in their entirety. The Government addresses each of the subpoenas separately but also lays out its opposition more broadly.

Essentially, the Government argues that four of the five subpoenas (the exception being the subpoena to CMS) are addressed at agencies which play no role in the automated processing of Medicare claims. Additionally, none of the subpoenas seek information relevant to the Government's actual payment decision. The Government states that each agency made timely objections but also produced several thousand pages of responsive documents and that the Government has referred Defendant to publicly available information to satisfy the inquiries.

Like Defendant, the Government predicates its opposition in part upon the Court's April 23, 2019 opinion. The Government maintains that the opinion followed the materiality analysis in *Universal Health Services, Inc. v. United States Ex Rel. Escobar* ("Escobar"), 136 S. Ct. 1989 (2016), an analysis which implicates whether "compliance with a particular statute or requirement actually matters to the Government or is otherwise 'minor or insubstantial.'"

However, the Government concedes that the Court left Bayer with a "narrow opening" based upon the *Escobar* factors, i.e., what actions the Government takes when it gains actual knowledge that certain requirements were violated. Bayer, says the Government, is mistakenly using this narrow opening to press for unnecessary discovery. In its demand for this broad discovery, according to the Government, Defendant mistakenly believes that it is entitled to probe into whether the Government "has ever denied payment" as a result of claims from kickbacks or off-label promotion. The Government insists that this is the wrong question. First, Government action is only relevant to the extent "it shows what the Government does when it knows of the fraud." Second, the Government action factor is not limited to what the Government did at the time the claim is submitted through an automated system "but rather it is evaluated based upon the full panoply of options available. . . to address payments due to error or

fraud[.]” In other words, as the Special Master interprets this argument, it is the Government’s position that its conduct in paying arguably inappropriate claims should only be evaluated after it becomes aware of a fraud, not when the claims are paid, which may occur years before the Government has knowledge of an actual fraud. Therefore, the Government insists Bayer is engaging in “boundless fishing expeditions” from agencies which have no bearing on a determination to pay claims when presented and prior to the Government’s actual knowledge of their impropriety.

In further support, the Government maintains that kickbacks are a “pernicious problem in federal healthcare programs” but difficult to identify since CMS processes hundreds of millions of claims each year through an automated system which cannot detect kickbacks. Additionally, the DRG system disguises the use of kickbacks in tainted claims.<sup>4</sup> The Government notes that Bayer has not even attempted to explain why it thinks that the Government knew of its fraud – which Bayer denies occurred – when the claims were initially processed.

As to Bayer’s argument that actual knowledge is relevant to its defense because the Government continued to pay Trasylol claims years after it learned of the allegations in this case in 2005 when Realtor filed her Complaint, the Government states that Bayer fails to explain why its subpoenas seek information from 1996 through July 2005 and that even after Realtor’s filing of the complaint, at most the Government would be on notice of allegations – not proof or actual knowledge – of improprieties. As to the Medicare program continuing to pay claims after the *qui tam* action, the Government argues that as a medical provider, important health and safety

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<sup>4</sup> DRG (Diagnosis-Related Group) is a “bundled system” for payment of hospital claims. Bayer has argued that the system precluded it from being liable under the FCA for kickbacks or for marketing promotional products for unapproved uses.



reasons obligate it to continue to pay claims. That is, “the Government does not enjoy the luxury of refusing to reimburse healthcare claims the moment it suspects there may be wrongdoing.” Citing *United States Ex. Rel. Longo v. Wheeling Hospital*, 2019 WL 4478843 (N.D. W. Va. Sept. 18, 2019).

The Government also argues that whether its employees were permitted to attend conferences (which Bayer argues undermines the notion that the conferences were disguised kickbacks), is irrelevant as to the materiality of AKS violations or the Government’s knowledge of the kickbacks. That is, the attendance of Government employees at conferences for any purpose does not explain why Bayer violated the AKS by paying kickbacks to physicians to induce prescribing of Traslolol or Avelox.

As to the individual subpoenas to the five agencies, the Government states as follows:

- The subpoena to CMS contained 30 wrongly worded requests, so broad as to encompass “virtually every document generated by CMS in administering the Medicare program over a 25 year period.” The Government has met and conferred with Defendant and has provided thousands of documents and spent countless hours searching for documents or links to responsive documents. CMS referred Bayer to a number of publicly available documents responsive to its specific requests and, as noted, “also repeatedly offered Bayer electronic claims data,” the best source of information for several of the requests. The same electronic resource has been made available to Realtor and CMS is in the process of furnishing electronic claims data to her.
- The Government separately addresses certain paper records “not covered by the Government’s October 3, 2019 motion to quash,” 800,000 boxes, consisting of over two billion pages of aged paper records scattered across 12 storage facilities. Of these, 16,000 boxes are of an unknown date range and approximately 800,000 date from 2000 to 2006. The Government maintains that the aged paper boxes contain the same categories of information as the aged paper records from 1996 to 1999 and, equally as important, “lack payment decisions and thus have no relevance to this case.” The Government maintains that an appropriately framed request for electronic claims data is more convenient, less burdensome and less expensive to produce. As of this point, the Government has not sought cost shifting as to any expenses of CMS as to the 16,000 boxes or the 2000 to 2006 aged paper records. They request that if the Court orders that

these boxes of aged paper records be retained by CMS or made available for Bayer's inspection that a cost shifting request should then be implemented.

- As to the FDA, "20 broad and burdensome requests" from 1996 to present were made. The Government maintains that the FDA does not make payment decisions and that Bayer has refused to narrow its subpoena or take any requests off the table. Also, contrary to Bayer's contention, the FDA has made three separate productions consisting of several thousand pages. Hence, the FDA has "more than complied" with its obligations. It also maintains that Bayer's effort to extract a statement from the FDA about whether "it had ever participated in CMS's decision to approve or deny payment for a claim on the basis of an alleged kickback or off-label use" is not a proper use of a subpoena.
- As to the DOJ, the subpoena contained "19 broad and burdensome requests," none relevant to the materiality inquiry. Again, as with the FDA, the DOJ does not make payment decisions. To the extent Bayer has sought a "better understanding of DOJ's view" of materiality, DOJ explained those views in briefs filed in this case.
- The Government also addresses Bayer's request for a proposed representation regarding the absence of DOJ's role in payment of Medicare claims in exchange for withdrawal of its subpoena. Despite receiving the proposal, Bayer refused to withdraw, defeating the purpose of further discussion. Then, in response to Bayer's claim that the DOJ failed to address the date on which it had knowledge of Realtor's allegations, the Government points out "Bayer obviously knows the date the *qui tam* complaint was filed in this case" and knowledge of the allegations is not relevant to Government action which requires actual knowledge.
- As to the DOD and VA subpoenas, which are almost identical and contain 17 separate requests, the Government points out that neither agency has any claims at issue in this case. The subpoenas sought documents relating to the agencies' review and approval of Trasyolol and Avelox. Therefore, the requests have no bearing on CMS's payment decisions and neither agency had any role in CMS's automated payment system. As to Defendant's speculation about off-label usage of Trasyolol by DOD and VA physicians, Defendant fails to explain how such usage bears on the "reasonableness and necessity" standard under Medicare. Instead, "The more plausible explanation for any such off-label use...is that it was the result of Bayer's allegedly illegal off-label promotion campaign rather than evidence that such uses are reasonable and necessary under Medicare."

#### IV. DEFENDANT'S REPLY

Defendant, in its reply papers, generally repeats the arguments voiced in its motion, but emphasizes these points.

- Contrary to the Government's position, it knows precisely what Bayer wants in discovery but is trying to withhold information since producing it would "devastate Realtor's meritless claims." Bayer insists that the Government has refused to provide even basic information as to whether CMS has ever denied payment due to an AKS or off-label violation.
- Bayer argues that it has served five subpoenas on five agencies only because regulations invoked by the Department of Justice required it to do so.
- Bayer addresses three limited areas of inquiry regarding the documentation: (1) whether CMS has ever denied payment for a violation; (2) whether it has a code in its database for denying payment due to an AKS or off-label violation; and (3) whether CMS ever investigates violations as part of its claim processing. Defendant believes that the answer to each question is no and that no documents exist. Therefore, Bayer insists the Government should acknowledge this.
- Bayer maintains that none of the CMS productions provide an adequate response. Bayer states the Government has taken inconsistent positions and its arguments are contrary to the law of the case – meaning Judge Linares' ruling on the parties' partial summary judgment motions and the order and opinion of the Special Master issued March 26, 2020. According to Defendant, these rulings stand for the proposition that "actual knowledge" only comes into play after Realtor meets her burden of providing evidence that Bayer "knows that the Government consistently refuses to pay claims in the mine run of cases" based on AKS or off-label violations. Once Realtor meets this burden, Bayer can raise "actual knowledge" as a defense. That is, "Bayer may try to rebut Realtor's evidence with proof that 'the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated' or evidence that 'the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated and has signaled no change in its position.'"
- Besides, says Bayer, at this point in discovery, there is no basis for the Government to refuse to provide basic facts. Only after those facts have been provided – meaning whether the Government has ever denied payment as a result of the violations – can the parties address issues at the heart of this lawsuit. In other words, at this phase, Bayer maintains it has a right to receive non-privileged, responsive discovery which may (or may not) support its defense and the Government should be obligated to provide information now so the parties can hash it out later.
- Specifically as to the DOJ, Bayer concedes that CMS is the agency that makes payment decisions and, therefore, CMS should be the focus of the materiality inquiry. However, Bayer insists it needs discovery from DOJ because "even if the Government is estopped from arguing that DOJ's views are relevant to materiality, "the Realtor may not be." Further, in *qui tam* cases, the DOJ conducts an investigation to determine whether to intervene so the DOJ presumably had actual knowledge of the conduct at issue.

- As to the VA, DOD and FDA, Bayer repeats its initial arguments. Bayer states that it intends to prove that off-label uses of Trasylol were supported by accepted medical practice and will provide proof through experts that hospitals regularly use the medication off-label. This argument would further be bolstered by use at VA and DOD hospitals. Similarly, if VA and DOD employees attended events run by Bayer or other manufacturers under those agencies' own policies "that would undercut any allegations that the events were illicit kickbacks."
- As to the FDA, records regarding conference attendance would undermine the notion that attendance was a disguised form of a kickback. Bayer emphasizes the FDA has produced only 302 documents, half of which are outside the time period at issue, and many are duplicative. When Bayer posed "several reasonable and basic questions" about this response and the FDA's search efforts, the agency "refused to respond."
- Bayer argues that any burden on the Government is minimal. If CMS has conducted "extensive searches," the agency need only confirm that it has never denied payment due to violations, has no code to that effect, and has never conducted an investigation to determine whether a violation resulted in a decision to refuse to pay a claim.
- As to the retention of paper records, "this issue has already been addressed in multiple briefs." Bayer goes on to state that the Government could have permitted "sampling or provided a stipulation" as to the paper documents and that the defendant will forgo these documents "if CMS confirms, that after its 'extensive searches,' it has none of the three types of documents stated above."

## V. OPINION

As all the litigants agree, *Rule 26* generally governs the scope of discovery in federal litigation. It provides:

Parties may obtain discovery regarding any non-privileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within the scope of discovery need not be admissible in evidence to be discoverable.

[*Rule 26(b)(1).*]

*Rule 26* is to be construed liberally in favor of disclosure since relevance is a broader inquiry at the discovery stage than at the trial stage. *Tele-Radio Sys. Ltd. v. DeForest Elecs., Inc.*, 92 F.R.D. 371, 375 (D.N.J. 1981). While relevant information need not be admissible at

trial in order to grant disclosure, the burden remains on the party seeking discovery to “show that the information sought is relevant to the subject matter of the action and may lead to admissible evidence.” *Caver v. City of Trenton*, 192 F.R.D. 154, 159 (D.N.J. 2000). Upon a finding of good cause, a court may order discovery of any matter relevant to a party’s claims, defenses or the subject matter involved in the action. “Although the scope of discovery under the Federal Rules is unquestionably broad, this right is not unlimited and may be circumscribed.” *Bader AG v. Betachem, Inc.*, 173 F.3d 188, 191 (3d Cir. 1999).

In this case, Defendant seeks to obtain discovery of documents from a non-party by way of a subpoena. Discovery sought via a subpoena issued pursuant to *Rule 45* must fall within the scope of discovery permissible under *Rule 26(b)*. *OMS Investments, Inc. v. Lebanon Seaboard Corp.*, Civ. No. 08–2681, 2008 WL 4952445 (D.N.J. Nov. 18, 2008). Under *Rule 45*, “courts have significant discretion” to quash or modify a subpoena where the discovery sought is irrelevant, or compliance with the Subpoena would be “unreasonable and oppressive.” *First Seabord Sur. v. Dunkin & Devries Ins. Agency*, 918 F. Supp. 2d 362, 383 (E.D. Pa. 2013).

In addition, under *Rule 45(d)(1)*, “[a] party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid opposing undue burden or expense on a person subject to the subpoena” and the Court has a responsibility to enforce this duty. However, it is the party claiming undue burden that must establish the same. *Nye v. Ingersoll Rand Company*, Civ. No. 08-3481, 2011 WL 253957 at \*1 (D.N.J. Jan. 25, 2011); *OMS Investments*, 2008 WL 44952445 at \*2. When a subpoena falls outside the scope of permissible discovery, the court has authority to quash or modify it upon a timely motion by the party served. *Rule 45(d)(3)*.

In applying *Rules* 26 and 45, the court must balance several competing factors in assessing the reasonableness of a subpoena: (1) relevance; (2) the party's need for the documents; (3) the breath of the document request; (4) the time period covered by it; (5) the particularity with which the documents are described; (6) the burden imposed; and (7) the subpoena recipients status as a non-party to the litigation. *Gould v. O'Neill*, No. Civ. 17-100, 2019 WL 4686991 at \*3 (D.N.J. Sept. 26, 2019) (citing *Biotechnology Value Fund, L.P. v. Celera Corp.*, No. Civ. 14-4046, 2014 WL 4272732 at \*2 (D.N.J. Aug. 28, 2014)).

Before addressing the competing factors in assessing the reasonableness of the subpoenas at issue here in more detail, the Special Master will address factor (7), the subpoena recipient's status as a non-party to the litigation. Defendant asserts in its submissions that the Government is the real party in interest since any recovery flows in its direction and because the Government has participated in this litigation by way of filing submissions with the Court, participating in oral argument and by seeking informal discovery from Bayer. This is not the first time that Defendant has advanced this argument before the Special Master in support of a motion to compel discovery. Nothing has changed in that regard. Therefore, as previously set forth in the Order and Opinion of the Special Master of March 26, 2020, pages 9–10, the Government has declined to intervene and the Special Master rejects Bayer's assertions that the Government should be treated as a party to this litigation because it is not a passive bystander. Hence, the reasoning below remains premised on the proposition that the Government is, in fact, a non-party recipient of the subpoenas issued by a party, Bayer.

Given this finding, this decision turns on balancing the other competing factors to assess the reasonableness of the subpoenas at issue. In order to make this assessment, as the parties

agree, the Special Master must look to the Order and Opinion of Judge Linares dated April 22, 2019, filed in the wake of competing cross-motions for summary judgment by Bayer and the Government. That Order and Opinion effectively establishes a framework in this action as to what Realtor must prove to establish her claim and as to what Bayer may establish in its defense.

In its decision, the Court rejected Bayer's assertion that the Government's diagnosis-related group (DRG) fixed fee payment system prohibited Realtor from proving that Bayer's alleged conduct would have been material to the Government's payment decision. The Court relied upon *Universal Health Servs., Inc. v. United States Ex. Rel. Escobar*, 136 S. Ct. 1989, 2004 (2016) ("Escobar"). The Court found that "realtor must provide 'evidence that [Bayer] knows that the Government consistently refuses to pay claims in the mine run of cases based on non-compliance with' the AKS or the reasonable and necessary requirement as it relates to off-label drug uses." *United States Ex. Rel. Simpson v. Bayer Corp.*, 376 F. Supp. 3d 392, 414 (D.N.J. 2019). The Court further explained that "Escobar instructs courts to examine the Government's practice of payment or nonpayment of claims based on the same underlying violation – claims that are noncompliant" with the particular statutory, regulatory, or contractual requirement. *Id.*

The focus of the inquiry is therefore not on the payment mechanism used in a given context, but rather on whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's decision to pay a claim. *Id.* (quotations omitted). Therefore, the focus is on "the Government's actual or likely conduct as to the payment of noncompliant claims with the AKS or with Medicare's reasonable and necessary requirement as to off-label drug uses – the two alleged underlying violations in this case." *Id.* at 415. The Court

went on to state that Defendant could rebut Realtor's evidence with proof that "the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated," or evidence that "the Government regularly pays a particularly type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in its position." *Id.* (quoting *Escobar*, 136 S. Ct. at 2003-04).

Although Defendant and the Government strongly disagree on the parameters or extent of its application, they concur that the materiality standard described by the Court governs here. So, as the Government concedes, there is indeed a "narrow opening" based upon the *Escobar* factors which permits a defendant to explore what actions the Government takes when it gains actual knowledge that certain requirements were violated. Hence, there remains a window – albeit a small window – left open for Bayer's inquiries into relevant Government action to rebut Realtor's assertions.

As described previously, Bayer has issued five subpoenas to Government agencies. While Defendant insists that each of these subpoenas are narrowly focused so that it limits the burden placed upon the Government to respond, the Special Master concludes that they are in fact rather broad, and overreaching, and should be modified to limit their scope.

Indeed, as the Government argues, Defendant's collective subpoenas could be read to require five Government agencies to produce every and any document which in any way reflects upon the payment or non-payment of medical goods and services which the Government, through its agencies, is obligated to reimburse under its healthcare services programs. Nor has Bayer adequately explained why electronic claims data and/or publicly available documents offered or identified by the Government is insufficient to satisfy a number of its demands.



Furthermore, Bayer has not demonstrated – and the Government clearly denies – that any agency other than CMS is responsible for or has, in fact, taken steps to deny payment of a claim as a consequence of an assertion that the claim violated the AKS or represented a payment for medically unnecessary (off-label) services. Those four other agencies have not been shown to have any role in the automated processing of claims and assert no claims here. Therefore, it is the actions (or inactions) of CMS which directly bear upon Realtor’s allegations and upon Bayer’s defenses. The vast majority of the inquiries here are, therefore, seemingly directed at agencies whose conduct need not be subject to scrutiny.

In its moving papers and more specifically in its reply, Bayer maintains that it is essentially inquiring into limited areas in its document requests, inquiries which, it says, may provide information in response to Realtor’s allegations and in defense of this action. The Special Master finds that at least as to these areas of inquiry, based upon Judge Linares’ prior decision in this matter and the Supreme Court’s decision in *Escobar*, Bayer is entitled to responses. Those areas of inquiry are as follows:

1. Whether CMS has ever denied payment for a violation of the anti-kickback statute;
2. Whether CMS has ever denied payment as a result of an off-label violation;
3. Whether CMS has a code in its database for denying payment due to AKS;
4. Whether CMS has a code in its database for denying payment due to an off-label violation;
5. Whether CMS has ever investigated violations (AKS or off-label) as part of its claims processing.

The Special Master, therefore, orders that Bayer’s subpoena to CMS be modified so as to limit the demands to documents responsive to these five questions. To the extent that Bayer’s

subpoenas seek information from CMS beyond these inquiries, the demands contained within these subpoenas are quashed.

As to the remaining agencies (FDA, DOJ, DOD and VA), Bayer's subpoenas are quashed except to the following extent:

As to the FDA, the agency is obligated to acknowledge whether it participated in any CMS decision to approve or deny payment for a claim on the basis of an alleged kickback or off-label use.

As to the DOJ, the agency is required to acknowledge or deny its participation in any decision as to Trasylol and Avelox.

As to the VA and DOD, they are obligated to provide any documents strictly related to review and approval of Trasylol and Avelox.

In light of the fact that the Special Master has modified these subpoenas, it would be prudent for the parties to meet and confer in order to reach agreement on the re-issuance of the subpoenas along the lines set forth above or to determine a mechanism and reasonable time frame for tailored responses. The Special Master will not at this time order such a conference but asks the parties to strongly consider doing so in order to move forward with this discovery issue.

## **VI. CONCLUSION**

For these reasons, the Special Master grants in part and denies in part both Defendant's motion to compel discovery and the Government's cross-motion to quash as described above.

Date: February 11, 2021

*/s/ Dennis Cavanaugh*  
DENNIS M. CAVANAUGH  
Special Master